UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION	**2:17-MD-2789 (CCC)(LDW) (MDL 2789)**
This Document Relates to:	**Judge Claire C. Cecchi**
***Rieder v. AstraZeneca Pharmaceuticals LP*, 2:19-cv-00850**	

REPORT AND RECOMMENDATION
OF SPECIAL MASTER ELLEN REISMAN REGARDING
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, and Merck Sharp & Dohme Corporation (collectively "Defendants") have filed a motion for summary judgment against Plaintiff James Rieder on multiple grounds other than preemption and statute of limitations, which are or will be addressed in separate Report and Recommendations.[1]

Plaintiff Rieder, in his Complaint, asserted claims for Strict Product Liability (Count I), Strict Product Liability – Design Defect (Count II), Strict Product Liability – Failure to Warn (Count III), Negligence (Count IV), Negligence *Per Se*

[1] Defs.' Mot. for Summary Judgment as to Pl. James Rieder, ECF No. 32 [hereinafter Defs.' Summ. J. Mot.].

(Count V), Breach of Express Warranty (Count VI), Breach of Implied Warranty (Count VII), Negligent Misrepresentation (Count VIII), Fraud and Fraudulent Misrepresentation (Count IX), Fraudulent Concealment (Count X), Violation of Ohio State Consumer Protection Laws (Count XI), as well as punitive damages.[2] Plaintiff Rieder has moved voluntarily to dismiss Counts II, IV, V, VII and XI,[3] and, as to those claims, I recommend that Defendants' motion be denied as moot. This Report and Recommendation will address only the six counts that remain in dispute, which are Counts I, III, VI, VIII, IX, and X.

I. LEGAL STANDARD/CONTROLLING LAW

"Summary judgment is appropriate only where . . . there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law."[4] The evidence of the non-moving party is to be trusted and all inferences shall be drawn in its favor.[5] The moving party bears the burden "of stating the basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact."[6] If the moving party meets this burden, the non-

[2] Rieder Compl. ¶ 14, ECF No. 1.
[3] PSC's Mot. to Voluntarily Dismiss Counts 2, 4, 5, 7, and 11 of Plaintiff Rieder's Complaint, No. 2:17-md-2789, ECF No. 718.
[4] *Melrose Inc. v. Pittsburgh*, 613 F.3d 380, 387 (3d Cir. 2010) (citing *Ruehl v. Viacom, Inc.*, 500 F.3d 375, 380 n.6 (3d Cir. 2007)).
[5] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986).
[6] *See Alley v. MTD Prods. Inc.*, No. 3:17-cv-3, 2017 U.S. Dist. LEXIS 208742, at *5 (W.D. Pa. Dec. 20, 2017) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)).

moving party "must set forth specific facts and present affirmative evidence demonstrating that there is a genuine issue for trial" and the non-moving party "may not rest upon the mere allegation[s] or denials of [his] pleading[.]"[7] For a court to consider an issue genuine, "there must be sufficient evidence . . . for a reasonable jury to find for the nonmovant."[8]

The parties agree that Ohio law applies to Plaintiff Rieder's substantive claims because he is an Ohio resident who took Nexium and allegedly suffered injury while living in Ohio.[9] I agree. The parties further agree that in Ohio product liability claims are governed by the Ohio Product Liability Act ("OPLA") which was enacted in 1998,[10] and that in 2005, OPLA was amended to make clear that all common law product liability claims were abrogated by OPLA.[11] Thus, both Plaintiff Rieder and

---

[7] *Denson v. Atl. Cnty. Dep't of Pub. Safety*, No. 13-5315, 2016 U.S. Dist. LEXIS 132181, at *11 (D.N.J. Sept. 27, 2016) (citations omitted).

[8] *Coolspring Stone Supply, Inc. v. Am. States Life Ins. Co.*, 10 F.3d 144, 148 (3d Cir. 1993).

[9] *See* Mem. of Law in Support of Defs.' Summ. J. Mot. 12-14, ECF No. 32-2 [hereinafter Defs.' Summ. J. Mem.]; PSC's Mem. in Opp'n to Defs.' Summ. J. Mot. 1, 2:17-md-02789, ECF No. 717-2 [hereinafter PSC's Summ. J. Opp'n Mem. in *Rieder*]. The PSC on behalf of Plaintiff Rieder, however, asserts that his claim for punitive damages should be governed by Delaware law. PSC's Summ. J. Opp'n Mem in *Rieder* 32-40. Defendants have now withdrawn their Motion for Summary Judgment as to Plaintiff Rieder's claim for punitive damages. Reply Mem. in Supp. of Defs.' Summ. J. Mot. 1 n.1 [hereinafter Defs.' Summ. J. Reply Mem.]. Consequently, the issue need not be addressed in this Report and Recommendation.

[10] Ohio Rev. Code 2307.71-80.

[11] Ohio Rev. Code 2307.71(B).

Defendants are in agreement that his product liability claims are governed exclusively by OPLA.

II. DISCUSSION AND ANALYSIS

A. Counts I, III, and VI

Defendants seek summary judgment on Counts I, III, and VI of the Rieder Complaint (for strict product liability, strict product liability failure to warn, and breach of express warranty, respectively) to the extent that they assert common law product liability claims that exceed what are permitted under OPLA.[12] The PSC has stated on behalf of Plaintiff Rieder that he is not asserting any claims in Counts I, III, and VI beyond what are authorized by OPLA,[13] and Defendants do not dispute that OPLA provides for and permits assertion of the types of claims alleged in Counts I, III, and VI.[14]

Thus, the only issue is whether Defendants are entitled to summary judgment as to these claims brought by Plaintiff Rieder under OPLA. For the reasons set forth below, I recommend that Defendants' motion for summary judgment as to Counts I

---

[12] Defs.' Summ. J. Mem. 23-24; *see* Ohio Rev. Code § 2307.71(B).
[13] PSC's Summ. J. Opp'n Mem. in *Rieder* 18-19.
[14] Defs.' Summ. J. Mem. 24; *see* OPLA § 2307.71(A)(13) (defining "Product Liability Claim" to include claims based on "[t]he design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product; [a]ny warning or instruction, or lack of warning or instruction, associated with that product; [a]ny failure of that product to conform to any relevant representation or warranty.")

and III be denied and that Defendants' motion for summary judgment as to Count VI be granted.

a. General and Specific Causation

Relying exclusively on their *Daubert* motions to exclude the testimony of Plaintiff Rieder's experts Dr. David Charytan and Dr. Derek Fine, Defendants contend that they are entitled to summary judgment because, without the testimony of Drs. Charytan and Fine, Plaintiff Rieder cannot carry his burden of proving either general or specific causation – *i.e.*, that Nexium can cause the kidney disease alleged by Plaintiff Rieder and that it actually did so in his case.[15] However, I have recommended that these *Daubert* motions be denied.[16] Accordingly, the predicate for Defendants' motion for summary judgment as to general and specific causation is lacking, and I therefore recommend that it be denied. Plaintiff Rieder has proffered sufficient potentially admissible contested evidence of both general and specific causation to create a question for the jury on this issue.

b. Failure to Warn

Defendants argue that Plaintiff Rieder's failure to warn claim fails because he cannot establish that Defendants' alleged failure to warn was a proximate cause of

[15] Defs.' Summ. J. Mem. Mem. 14-16.
[16] Report and Recommendation of Special Master Ellen Reisman Regarding *Daubert* Mots. 71, 88, No. 2:17-md-2789, ECF No. 811.

his injury.[17] With regard to claims involving prescription drugs, Ohio law has adopted the "learned intermediary doctrine," which "provides that a drug manufacturer satisfies its duty to warn of known risks by providing an adequate warning to the medical professional of the risks associated with the drug's use."[18] To succeed on a failure to warn claim, a plaintiff must establish proximate cause between the plaintiff's ingestion of a drug and the plaintiff's injury.[19] Ohio law analyzes proximate cause as two sub-issues: "(1) whether lack of adequate warnings contributed to the plaintiff's ingestion of the drug, and (2) whether ingestion of the drug constitutes a proximate cause of the plaintiff's injury."[20]

Importantly, Ohio law has also adopted a "heeding presumption" in prescription drug cases that presumes that treating physicians would have taken

---

[17] *See* Defs.' Summ. J. Mem. Mem. 16-20. "Under Ohio law, a plaintiff asserting a products liability claim[] based on failure to provide adequate warnings not only must convince the fact finder that the warning provided is unreasonable, hence inadequate, but he also must establish the existence of proximate cause between the [product] and the fact of the plaintiff's injury." *Hisrich v. Volvo Cars of N. Am., Inc.*, 226 F.3d 445, 450 (6th Cir. 2000) (alterations in original) (internal quotation marks and citations omitted).

[18] *Fulgenzi v. PLIVA, Inc.*, 140 F. Supp. 3d 637, 648-49 (N.D. Ohio 2015); *see* Ohio Rev. Code § 2307.76(C) ("An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.").

[19] *See Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 936 (S.D. Ohio 2010); *see also Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 838 (Ohio 1981).

[20] *Seley*, 423 N.E.2d at 838.

account of an adequate warning in deciding upon a recommended course of treatment.[21]

> [W]here no warning is given, or where an inadequate warning is given, a rebuttable presumption arises, beneficial to the plaintiff, that the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug. This presumption, absent the production of rebutting evidence by the defendant, is sufficient to satisfy the first branch of the plaintiff's proximate cause burden.[22]

In other words, the heeding presumption shifts the burden to a defendant to proffer affirmative evidence that a physician would not have acted differently had a different warning been provided.[23]

A defendant can rebut the heeding presumption by showing that "an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter."[24]

> [W]here the evidence demonstrates that 'an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter, the

---

[21] *Id.*
[22] *Id.*
[23] *See, e.g., Williams v. Lederle Labs.*, 591 F. Supp. 381, 386 (S.D. Ohio 1984) ("If the *defendant* does not present rebutting evidence, the presumption satisfies the plaintiff's burden of demonstrating that the inadequate warning was the proximate cause of the ingestion of the drug.") (emphasis added); *Hisrich*, 226 F.3d at 451 (applying Ohio law in a product liability case involving automobiles and noting "[t]he lack of evidence that [plaintiff] read or did not read the instructions, however, does not rebut the presumption, but rather establishes it in [plaintiff's] favor. Defendants ignore that they must rebut the presumption and that plaintiff is not required to present evidence establishing what is presumed unless such rebuttal evidence is presented.").
[24] *Seley*, 423 N.E.2d at 838.

> presumption. . . is rebutted, and the required element of proximate cause between the warning and ingestion of the drug is lacking.[25]

The presumption can be rebutted and summary judgment granted "[w]here a treating physician unequivocally testifies that an adequate warning would not have altered the course of treatment."[26]

Moreover, under Ohio law, analyzing physician behavior is not simply a determination of whether a physician would or would not have prescribed a drug if there had been a different warning. Rather, Ohio law looks to whether a physician would have responded differently to an adequate warning.[27] For example, courts have found that a genuine issue of material fact is created sufficient to defeat summary judgment when there is evidence that a physician a) would monitor patients differently,[28] b) would have discussed the potential side effects with a patient,[29] c)

---

[25] *Miller*, 759 F. Supp. 2d at 936.
[26] *Mathews v. Novartis Pharms. Corp.*, No. 3:12-cv-314, 2013 U.S. Dist. LEXIS 153519, at *30-31 (S.D. Ohio Sept. 25, 2013) (citing *Miller*, 759 F. Supp. 2d at 936).
[27] *See Monroe v. Novartis Pharms. Corp.*, 29 F. Supp. 3d 1115, 1127 (S.D. Ohio 2014) (quoting *Williams*, 591 F. Supp. at 386-87).
[28] *See Coon v. Pfizer, Inc.*, No. 1:17-cv-125, 2019 U.S. Dist. LEXIS 24255, at *7-8 (S.D. Ohio Feb. 14, 2019) ("[Doctor's] testimony that he monitors his patients differently now allows for the inference that, had he been adequately warned, he would have changed his monitoring procedures for [Plaintiff], which may have prevented his injury.") (internal citation omitted).
[29] *See Bowles v. Novartis Pharms. Corp.*, No. 3:12-cv-145, 2013 U.S. Dist. LEXIS 134350, at *33-34 (S.D. Ohio Sept. 19, 2013) (finding genuine issue of material fact where physician testified he "generally discusses the side effects of medications" with patients such that a jury could infer that physician would have discussed with plaintiff); *Sheffer v. Novartis Pharms. Corp.*, No. 3:12-cv-238, 2013 U.S. Dist.

would have warned the patient about a risk, and would have reduced the frequency or dosage of a drug.[30] In the context of prescription medications, the focus on whether a physician's behavior would have changed in some manner short of deciding not to prescribe a drug makes sense. All prescription medications carry some risk and, after consultation about the potential risks and benefits of a particular drug with a patient, a physician and her patient may still determine that the benefits of a drug outweigh the risk for that individual, but a physician may recommend a different dosage or frequency of a drug, or may engage in monitoring efforts that she otherwise would not have done. Determining whether a physician would have altered her conduct in the presence of an adequate warning may turn on the physician's credibility, and assessments of a witness' credibility are not appropriate at the summary judgment stage.[31]

LEXIS 133760, at *34 (S.D. Ohio Sept. 18, 2013) (denying summary judgment when "a reasonable jury could find that if [defendant] had issued a different warning, [prescribing physician] would have disclosed the risk of ONJ to [plaintiff], who would have refused to take [the drug], thereby averting her injury entirely.").

[30] *See Monroe*, 29 F. Supp. 3d at 1127 (finding genuine issue of fact where physician had changed his practice since new warnings were provided, now warns patients of the newly-added risk, and reduces the frequency of dosage for some patients).

[31] *See Williams*, 591 F. Supp. at 387 ("What [the treating physician] might or might not have done involves to some degree his credibility. Thus, we conclude that it is for the jury to determine whether the presence of an adequate warning would have made no difference in [the physician's] decision."); *Miller*, 759 F. Supp. 2d at 936 ("[W]here the evidence does not affirmatively establish that the prescribing physician 'would not have behaved differently had he received a different warning[,]' a matter of credibility may exist that is 'better made by the finder of fact.'" (quoting *Williams*,

In the instant case, three different physicians prescribed Nexium to Plaintiff Rieder at various points in time: Dr. Daniel Konold, Dr. Jay Wallin, and Dr. Richard Oberlander. Dr. Konold prescribed and/or provided Nexium samples to Plaintiff Rieder as early as April 2002.[32] Subsequently, Dr. Wallin continued Plaintiff Rieder's Nexium prescription from about September 2008 to August 2010.[33] When Dr. Wallin left his practice, his former partner, Dr. Oberlander, continued Plaintiff Rieder's prescription from about August 2010 to August 2014.[34]

Defendants contend that the testimony of two of Plaintiff Rieder's prescribing physicians, Drs. Wallin and Oberlander, rebuts the heeding presumption and shows that a different warning would not have affected their prescribing decisions.[35] The PSC, on behalf of Plaintiff Rieder, counters that Defendants have failed to address the heeding presumption with respect to Plaintiff Rieder's initial treating physician, Dr. Konold, who first prescribed Nexium to him.[36] Dr. Konold is deceased and was not able to be deposed. With regard to the two other physicians who prescribed

---

591 F. Supp. at 387)); *Monroe*, 29 F. Supp. 3d at 1127 ("[I]t is a matter of credibility for the jury to determine whether [the physician], given an adequate warning, would still have prescribed [the drug] to [plaintiff], despite his affidavit stating otherwise. It is similarly a matter of credibility whether he would have exercised more caution in monitoring [plaintiff].").

[32] Defs.' Summ. J. Mem. 5; PSC's Summ. J. Opp'n Mem. in *Rieder* 6-7.

[33] Defs.' Summ. J. Mem. 17; PSC's Summ. J. Opp'n Mem. in *Rieder* 8.

[34] Defs.' Summ. J. Mem. 19; PSC's Summ. J. Opp'n Mem. in *Rieder* 10 n.18.

[35] Defs.' Summ. J. Mem. 17.

[36] PSC's Summ. J. Opp'n Mem. in *Rieder* 6-8.

Nexium to Plaintiff Rieder, Drs. Wallin and Oberlander, the PSC argues that Defendants' characterization of Ohio law as it relates to "unequivocal" physician testimony is inaccurate but, in any event, neither Dr. Wallin nor Dr. Oberlander provided "unequivocal" testimony sufficient to rebut the heeding presumption.[37] Having considered the parties' briefs and oral arguments and undertaken a careful review of Ohio law, I conclude that sufficient disputed issues of material fact exist to preclude summary judgment on this issue.

1. Dr. Konold

In their opening brief, Defendants do not address or discuss Dr. Konold. The PSC contends that, because there is no testimony – let alone "unequivocal testimony" from Dr. Konold, who is deceased and was never deposed – Defendants have failed to rebut the "heeding presumption" and their motion must be denied.[38]

A threshold question is how the absence of testimony by the deceased Dr. Konold affects the "heeding presumption" under Ohio law. The PSC contends that Defendants cannot rebut the heeding presumption because they lack any testimony from Dr. Konold, and therefore the presumption remains, thereby creating a triable issue of fact with respect to whether any failure to give an adequate warning could have been a proximate cause of Plaintiff Rieder's injuries.[39] In their reply brief,

[37] PSC's Summ. J. Opp'n Mem. in *Rieder* 17-18.
[38] PSC's Summ. J. Opp'n Mem. in *Rieder* 6-8.
[39] PSC's Summ. J. Opp'n Mem. in *Rieder* 7.

Defendants cite cases from other jurisdictions stating that it is a plaintiff's burden to prove that an inadequate warning was the proximate cause of his injuries, that the unavailability of physician witnesses does not eliminate the burden, and that the PSC's position improperly transforms the rebuttable presumption into an irrebuttable presumption.[40] However, none of the cases cited by Defendants apply Ohio law, and many involve the law of jurisdictions that lack or have explicitly rejected a heeding presumption similar to that provided for by Ohio law.[41] The Sixth Circuit artfully stated the concern regarding citing cases applying other states' substantive laws: "Not only are these cases enormously fact-specific and fact-intensive, they are *state*-specific: the same set of facts that could get a plaintiff to the jury in one jurisdiction could very well result in summary judgment for the drug manufacturer in another.

[40] Defs.' Summ. J. Reply Mem. 4-5 n.6.

[41] *Hubbard v. Bayer HealthCare Pharms. Inc.*, 983 F.3d 1223, 1237–39 (11th Cir. 2020) (applying Georgia law and explicitly rejecting any heeding presumption); *Meade v. Ethicon, Inc.*, No. 4:20-cv-00694, 2021 U.S. Dist. LEXIS 179320, at *8-9 (E.D. Ark. Sept. 21, 2021) (applying Arkansas law with no mention of the state law's heeding presumption); *Shahbaz v. Johnson & Johnson*, No. 13-cv-07382, 2020 U.S. Dist. LEXIS 186475, at *36-37 (C.D. Cal. Jul. 31, 2020) (applying California law, which does not recognize heeding presumption); *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, 2017 U.S. Dist. LEXIS 8122, at *41 (S.D. W. Va. Jan. 20, 2017) (applying West Virginia law, which does not recognize the heeding presumption); *Sauls v. Wyeth Pharms., Inc.*, 846 F. Supp. 2d 499, 503 (D.S.C. 2012) (applying South Carolina law and explicitly rejecting any heeding presumption); *Leffler v. Am. Home Prods. Corp.*, 2005 Phila. Ct. Com. Pl. LEXIS 485, at *15-16 (Phila. Ct. Com. Pl. Oct. 20, 2005) (applying Pennsylvania law and noting that "Pennsylvania courts have consistently declined to apply any heeding presumption in pharmaceutical and most other product liability cases….").

Woe to the party in a failure-to-warn case who think that cases from other jurisdictions will guarantee victory in her own."[42]

Neither party cited to a case on point, that is, a case 1) applying Ohio law, 2) where the heeding presumption was in effect, but 3) a deceased physician could not be deposed to either reinforce or rebut the heeding presumption. And, I have found none. Defendants cite to *Heide* for the proposition that Ohio's heeding presumption does not alter a plaintiff's obligation to adduce sufficient evidence of causation in a failure to warn claim to avoid summary judgment.[43] In *Heide*, the Northern District of Ohio, applying Ohio law, granted summary judgment for defendant Ethicon on plaintiff's failure to warn claim because plaintiff failed to depose her physician and so could not demonstrate "that her physician would have acted differently had he been given an adequate warning."[44] Oddly, the *Heide* decision makes no mention whatsoever of Ohio's heeding presumption, despite citing other Ohio cases that explicitly discuss the presumption.[45] In this regard, *Heide* appears to be an outlier, and so I do not find it persuasive in this case.

---

[42] *Payne v. Novartis Pharms. Corp.*, 767 F.3d 526, 528 (6th Cir. 2014) (emphasis in original) (noting, in a case applying Tennessee substantive law, that biophosphonate cases from other jurisdictions were "not particularly helpful" in answering whether summary judgment was appropriate under Tennessee law).
[43] Defs.' Summ. J. Reply Mem. 4.
[44] *Heide v. Ethicon*, No. 4:20-cv-160, 2020 U.S. Dist. LEXIS 48402, at *11 (N.D. Ohio Mar. 20, 2020).
[45] *See Heide* at *10-11 (citing *Fulgenzi*, 140 F. Supp. 3d at 648 and *Sheffer*, 2013 U.S. Dist. LEXIS 133760, at *30).

The Ohio Supreme Court has stated that the point of the heeding presumption is to create a presumption "beneficial to plaintiff" on the element of proximate causation absent evidence rebutting it.[46] Though not on point, the cases cited by Defendants are instructive for a different reason. In *Meade*,[47] *Mullins*,[48] and *Sauls*,[49] each court granted summary judgment in favor of the defendant because plaintiffs could not adduce testimony that their treating physicians' decisions would have been affected by different warnings when the physicians were deceased and so unable to be deposed. In those cases, which did not involve a heeding presumption, the burden to adduce evidence fell on the plaintiffs and, due to no fault of the plaintiffs, they were not able to produce such evidence and so their claims failed. But, as previously noted, the Ohio heeding presumption shifts the burden to *defendants* to demonstrate evidence that a different warning would not have altered a physician's behavior.[50] Here, Defendants have not identified any evidence, through testimony or otherwise,

---

[46] *Seley*, 423 N.E.2d at 838.
[47] *See Meade*, 2021 U.S. Dist. LEXIS 179320, at *11-12.
[48] *See Mullins*, 2017 U.S. Dist. LEXIS 8122, at *41.
[49] *See Sauls*, 846 F. Supp. 2d at 502-03.
[50] *See Seley*, 423 N.E.2d at 838 ("This presumption, absent the production of rebutting evidence by the defendant, is sufficient to satisfy the first branch of the plaintiff's proximate cause burden.") (internal citation omitted); *Williams*, 591 F. Supp. at 386 ("If the defendant does not present rebutting evidence, the presumption satisfies the plaintiff's burden of demonstrating that the inadequate warning was the proximate cause of the ingestion of the drug."); *Hisrich*, 226 F.3d at 451 (applying Ohio law in a product liability case involving automobiles and noting "Defendants ignore that they must rebut the presumption and that plaintiff is not required to present evidence establishing what is presumed unless such rebuttal evidence is presented.").

that Dr. Konold's conduct in treating Plaintiff Rieder would have been the same despite a different warning. As such, Defendants have failed to rebut the heeding presumption and so are not entitled to summary judgment on Plaintiff Rieder's failure to warn claims.

2. Dr. Wallin

Even if Defendants had successfully rebutted the heeding presumption with regard to Dr. Konold, summary judgment would still be inappropriate because of the testimony of Dr. Wallin, the second physician to prescribe Nexium for Plaintiff Rieder. To warrant summary judgment on Plaintiff Rieder's failure to warn claim, Ohio case law indicates that Defendants need to demonstrate that *each and every physician* who prescribed Nexium would not have changed his behavior in the presence of a different warning.[51] Based on the record evidence, and taking all inferences in Plaintiff Rieder's favor, as I must on a motion for summary judgment, I believe there is a genuine issue of material fact regarding whether Dr. Wallin would have altered his treatment of Plaintiff Rieder had he been warned of potential kidney

[51] *See e.g.*, *Fulgenzi*, 140 F. Supp. 3d at 650 (granting summary judgment for defendant when all three physicians who prescribed drug to plaintiff testified that they did not review the manufacturer's warnings); *Bowles*, 2013 U.S. Dist. LEXIS 134350, at *33-34 (denying summary judgment where plaintiff's prescribing oncologist testified he still would have prescribed the drug even if he knew of risk of ONJ but evidence indicated plaintiff's dentist would have not proceeded with tooth extraction if oncologist and dentist knew that invasive dental procedures often trigger ONJ).

risks associated with PPI use. Dr. Wallin's testimony demonstrates that he did not provide "unequivocal" testimony that a different warning would not have changed his course of treatment.

On the one hand, Dr. Wallin testified that he had "continued the medication" prescribed by Dr. Konold because Mr. Rieder "was apparently okay with it"; that he still considered Nexium to be a safe and effective medication "[g]enerally"; and that nothing he heard at the deposition caused him to "question [his] decision to prescribe Nexium to the plaintiff."[52]

On the other hand, however, Dr. Wallin testified that he "would like to know if a medication can cause kidney injury," the frequency with which a drug could cause kidney injury, and the severity of the alleged kidney injury.[53] He also testified that "from a customary practice, I would have discussed any and all medications that could contribute to renal function – deterioration of renal function."[54] Considering Dr. Wallin's testimony that, in light of Plaintiff Rieder's 2008 blood work indicating renal insufficiency, he would have recommended that Plaintiff Rieder avoid NSAIDs because of their "well-documented history of causing renal insufficiency," a jury could reasonably conclude that, had Dr. Wallin been warned of the risk of kidney

[52] PSC's Br. Opposing Defs.' Mot. for Summ. J. on Failure to Warn Preemption, Ex. 284, 68:17-69:18 [hereinafter Wallin Dep.] No. 2:17-md-2789, ECF No. 731-38.
[53] Wallin Dep. 46:8-47:22.
[54] Wallin Dep. 28:2-12.

injury from PPI use, Dr. Wallin would have likewise advised Plaintiff Rieder to avoid or limit PPI medications.[55] In addition, in light of additional blood work in 2008 that indicated to Dr. Wallin that Plaintiff Rieder had possible development of CKD, Dr. Wallin testified that it would be his practice to discuss potential risk factors for renal function, such as ACE inhibitors.[56] Finally, Dr. Wallin testified that if Nexium had carried a warning regarding kidney risk, he would have passed that warning on to Plaintiff Rieder.[57] Such testimony is sufficient to create a genuine issue of fact as to whether Dr. Wallin would have altered his behavior had there been a different warning.

When Dr. Wallin's testimony is considered along with Plaintiff Rieder's testimony that he would have stopped taking Nexium if he had been informed that Nexium could be damaging to his kidneys,[58] Ohio case law indicates that summary judgment is not warranted. "Courts have found that where additional information from a treating physician would have dissuaded a patient from moving forward with a medical procedure, this is sufficient to defeat summary judgment, despite the doctor's recommendation."[59] In *Mathews*, for example, plaintiff's physician testified

[55] Wallin Dep. 18:22-19:15.
[56] Wallin Dep. 21:7-20.
[57] Wallin Dep. 70:24-71:20 ("But a warning I would have passed on.").
[58] Rieder Dep. 189:18-190:12.
[59] *McFarland v. Ethicon, Inc.*, No. 2:20-cv-02188, 2020 U.S. Dist. LEXIS 138448, at *6 (S.D. Ohio Aug. 4, 2020) (denying summary judgment for defendant when

that, had he known of the risk of ONJ from Aredia consumption, he would have discussed that risk with plaintiff.[60] Plaintiff testified that if his physician had warned him that Aredia might cause ONJ, "he would have refused to take it, despite his doctor's recommendation."[61] The court denied defendant's motion for summary judgment, concluding that plaintiff's testimony was "sufficient to create a genuine issue of material fact about whether his use of the drug was caused by the allegedly inadequate warning. A reasonable jury could find that if [defendant] had disclosed the risk of ONJ, [plaintiff's doctor] would have discussed the risk with [plaintiff] and [plaintiff] would have refused to take Aredia, thereby altering his course of treatment."[62] Similarly in *Sheffer*, the court denied defendant's motion for summary judgment because "[a] reasonable jury could find that if [defendant] had issued a different warning, [plaintiff's doctor] would have disclosed the risk of ONJ to [plaintiff], who would have refused to take Zometa, thereby averting her injury entirely."[63] Thus, Dr. Wallin's testimony that he would have "passed on" a warning regarding PPI use and kidney risk to Plaintiff Rieder, coupled with Plaintiff Rieder's testimony that, if his physicians had warned him that Nexium could cause kidney

---

plaintiff's physician testified that he would have wanted to know about potential mesh shrinkage and would have relayed that risk to his patients).

[60] *Mathews*, 2013 U.S. Dist. LEXIS 153519, at *31-32.

[61] *Id.* at 32.

[62] *Id.* at 32-33.

[63] *Sheffer*, 2013 U.S. Dist. LEXIS 133760, at *34.

damage, he would not have taken the drug, render summary judgment unwarranted here.

3. Dr. Oberlander

Dr. Oberlander was the third and final doctor to prescribe Nexium to Plaintiff Rieder. Dr. Oberlander's testimony is simply not clear as to whether his course of conduct as to Plaintiff Rieder would have been different in the face of a different warning. When asked "[I]f you had concerns regarding some of the risks of Nexium on August 10th of 2010 [when he began prescribing Nexium to Plaintiff Rieder] . . . would you have discussed those concerns with Mr. Rieder?" he responded, "It's hard to answer because 2010 I felt like Nexium was a good drug, and I still think it's a decent drug. So I'm not sure really how to answer that . . . ."[64] Dr. Oberlander was then asked what he "would have done different" when asked to refill Plaintiff Rieder's prescription in August 2010 if he had been told that Nexium could cause "serious renal injury, including chronic kidney disease".[65] His answer is not a model of clarity:

> Well, you know, I mean, that's been a few years ago and many patients ago, but based on how I practiced then and how I practice now, I still use proton pump inhibitors because they're much – they're superior to H2 blockers; they've improved quality of life. And I don't have a lot of chronic renal issues in my practice, per se, based on my prescribing, so

[64] PSC's Br. Opposing Defs.' Mots. for Summ. J. on Failure to Warn Preemption, Ex. 285 at 29:23-30:10 [hereinafter Oberlander Dep.], No. 2:17-md-2789, ECF No. 731-39.

[65] Oberlander Dep. 42:15- 43:1.

> if I use that as my foundation, I would tell you I would still prescribe the Nexium because it was working for him, so . . . .[66]

He was then asked whether he would have considered such a warning in his "risk/benefit analysis for Mr. Rieder."[67] Again, his response is somewhat murky:

> You know, again, that is the risk versus benefit and, you know, if something is a 1 or a 3 percent risk, that means there's 97 percent chance it won't happen. And so the benefit of using it outweighs the risk of using it, so – and, again, that's – it's hard to look back at 2010 when we're in 2021 – or 2020, and I can only tell you that the mindset then is we used proton pump inhibitors because it was – again, it was a much better drug class when treating gastroesophageal reflux disease.[68]

He went on to note that his analysis is different when he is considering a refill versus a new prescription.[69]

Taken in its entirety, Dr. Oberlander's testimony is supportive of the proposition that he would have refilled Plaintiff Rieder's prescription for Nexium even if there had been a different warning. But, it does not answer the question of whether his course of treatment would have been different in other ways, such as discussing the risk with Plaintiff Rieder. On balance, it seems insufficient to rebut the heeding presumption. But, even if it were sufficient, the heeding presumption has not been rebutted as to Drs. Konold and Wallin, and that fact alone, under Ohio

---

[66] Oberlander Dep. 43:4-14.
[67] Oberlander Dep. 43:18-44:3.
[68] Oberlander Dep. 44:7-17
[69] Oberlander Dep. 45:13-46:12.

law, is a sufficient basis for me to recommend that Defendants' motion for summary judgment as to Plaintiff Rieder's failure to warn claims be denied.

c. Express Warranty

OPLA permits claims for breach of express warranty when "[a] product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation."[70] Ohio courts have identified a four element test that plaintiffs must meet to recover for "nonconformance with representation" under OPLA: "1) that the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's products; 2) that the product did not conform to that representation; 3) that the plaintiff justifiably relied on that representation; and 4) that the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries."[71] "A general warranty of 'good, safe and merchantable quality' has been held to be insufficient to constitute an express representation under Ohio Revised Code Section 2307.77."[72]

---

[70] Ohio Rev. Code 2307.77.
[71] *Monroe,* 29 F. Supp. 3d at 1128.
[72] *Id.* (citing *Saraney v. TAP Pharm. Prods., Inc.*, No. 1:04-cv-02026, 2007 U.S. Dist. LEXIS 3113, at *24 (N.D. Ohio Jan. 16, 2007) ("The [Plaintiffs'] bare allegation,

The PSC on behalf of Plaintiff Rieder has pointed to a television commercial for Nexium "touting benefits with no mention of possible kidney disease" and a pharmaceutical sales representative's representations to doctors that Nexium is safe but not mentioning kidney disease as evidence of an express warranty.[73]

Under Ohio law, such representations by Defendants are insufficient to create an express warranty. A "general warranty of 'good, safe and merchantable quality'" is insufficient to constitute an express representation under OPLA.[74] As Defendants point out, Ohio law is clear that there must be an affirmative representation, not merely a general statement that a product is safe or appropriate: "Here, plaintiffs have not presented any evidence that Central Mills made an express representation about the shirt purchased by [Plaintiff]. Plaintiffs argue that in designing and marketing the shirt at issue, [Defendant] represented and warranted that the shirt was appropriate and safe to be worn by children. But because this does not constitute an express representation, [Defendant] is entitled to summary judgment."[75] I conclude that the examples cited by the PSC on behalf of Plaintiff Rieder are simply general assertions

---

contained in their complaint, that [Defendant] generally warranted Lupron of 'good, safe and merchantable quality' is insufficient to prove the express representation necessary to meet the standards laid down in O.R.C. § 2307.77.")).

[73] PSC's Summ. J. Opp'n Mem. in *Rieder* 29.

[74] *See Monroe*, 29 F. Supp. 3d at 1128 (citing *Saraney*, 2007 U.S. Dist. LEXIS 3113, at *24); *see* Defs.' Summ. J. Reply Mem. 19.

[75] *Patterson v. Central Mills, Inc.*, 112 F. Supp. 2d 681, 691 (N.D. Ohio 2000) (internal citation omitted).

of safety, not an express representation about Nexium. Not mentioning the risk of kidney injury is not the same as an express representation. For this reason, I recommend that Defendants' motion for summary judgment be granted as to Count VI.

B. Counts VIII, IX, and X

Defendants seek summary judgment on Plaintiff Rieder's claims for negligent misrepresentation (Count VIII), fraud/fraudulent misrepresentation (Count IX), and fraudulent concealment (Count X), on the ground that OPLA abrogates all such claims.[76] Plaintiff Rieder does not dispute that product liability claims are abrogated by OPLA.[77] A "product liability claim" under OPLA includes a cause of action for personal injury that allegedly arose from "[a]ny warning or instructions, or lack of warning or instruction, associated with that product."[78] Plaintiff Rieder does argue

[76] Defs.' Summ. J. Mem. 30-31, 33-35.

[77] PSC's Summ. J. Opp'n Mem. in *Rieder* 19 (citing *Meta v. Target Corp.*, No. 4:14-cv-0832, 2015 U.S. Dist. LEXIS 178781, at *3 (N.D. Ohio Mar. 23, 2015)).

[78] *See* Ohio Rev. Code Ann. § 2307.71(A)(13) (defining "Product liability claim" as

> "a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;

that his claims for negligent misrepresentation, fraud or fraudulent misrepresentation, and fraudulent concealment are not abrogated by OPLA because these claims are not product liability claims based on a failure to warn, but rather based on Defendants' "duty not to deceive doctors and patients."[79]

Plaintiff's complaint adopts the allegations in the master complaint[80] filed in MDL 2789. The core of Plaintiff Rieder's negligent misrepresentation claim (Count VIII) is that Defendants made statements about their PPI products; safety and efficacy in sales and marketing campaigns that were purportedly false because the products "ha[ve] a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff[]."[81] The core of Plaintiff Rieder's fraud / fraudulent misrepresentation claim (Count IX) is that Defendants made statements about their products' safety and efficacy that were purportedly false because the product "had not been sufficiently tested, w[as] defective in nature and/or [it] ***lacked adequate and/or sufficient warnings.***"[82] In short, Plaintiff Rieder's two misrepresentation claims boil down to the same thing –

(c) Any failure of that product to conform to any relevant representation or warranty.").

[79] PSC's Summ. J. Opp'n Mem. in *Rieder* 19.

[80] Pls.' Master Long Form Compl. and Jury Demand, ¶¶ 406-16 (Negligent Misrepresentation), 417-29 (Fraud and Fraudulent Misrepresentation), 430-55 (Fraudulent Concealment), No. 2:17-md-2789, ECF No. 118.

[81] Pls.' Master Long Form Compl. and Jury Demand ¶ 412.

[82] Pls.' Master Long Form Compl. and Jury Demand ¶ 426 (emphasis added).

that Defendants made statements about the safety and efficacy of their PPI products that were false or incomplete because they failed to include an adequate warning regarding the risks of kidney injuries. The core of Plaintiff Rieder's fraudulent concealment claim (Count X) is that Defendants suppressed and concealed safety information about the purported "high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders"[83] and therefore violated a duty to disclose information regarding potential adverse effects to Plaintiff Rieder and his healthcare providers.[84]

Plaintiff Rieder acknowledges that courts have found similar misrepresentation and fraud claims abrogated by OPLA. In *Johnson v. Eli Lilly*, the plaintiff had asserted that the defendant in that case was aware or should have been aware of the risks of adverse side effects from its drug, but failed to disclose those risks in its marketing materials, which were purportedly false because they proclaimed no association with the purported side effects.[85] The court found that the plaintiff's fraudulent misrepresentation claim was abrogated by OPLA because it was essentially a product liability claim based on a duty to warn.[86]

---

[83] Pls.' Master Long Form Compl. and Jury Demand ¶ 432.
[84] Pls.' Master Long Form Compl. and Jury Demand ¶¶ 439-40.
[85] *Johnson v. Eli Lilly*, No. 1:14-cv-453, 2015 U.S. Dist. LEXIS 30537, at *4-5 (S.D. Ohio Mar. 12, 2015).
[86] *Id.* at *5-6 (citing *Hogue v. Pfizer*, Inc., 893 F. Supp. 2d 914, 918 (S.D. Ohio 2012)).

In *Hendricks v. Pharmacia Corp.*, the plaintiff alleged that the defendants committed fraud by concealing material facts from consumers related to potential side effects from their drugs.[87] The court held that such allegations by plaintiff were rooted in failure to warn and thus abrogated by OPLA.[88] The court also held that the plaintiff's claims that the defendants engaged in active misrepresentations in the advertising, marketing, distribution, and sale of their drugs were also abrogated because they focused on the defendants' failure to warn of purported adverse effects.[89]

The case of *Stratford v. SmithKline Beecham Corp.*[90] is also illustrative. In that case, the court held that the plaintiff's allegations of fraudulent omission were abrogated by OPLA because they were essentially claims that the defendants had failed to provide an adequate warning of purported adverse effects associated with its drug.[91] The court also held that the plaintiff's allegations of active misrepresentations were not sufficiently pled because they contained general allegations but not specific

[87] *Hendricks v. Pharmacia Corp.*, No. 2:12-cv-613, 2014 U.S. Dist. LEXIS 76125 *10 (S.D. Ohio Jun. 4, 2014).
[88] *Id.* at *11.
[89] *Id.* at *11-12.
[90] *Stratford v. SmithKline Beecham Corp.*, No. 2:07-cv-639, 2008 U.S. Dist. LEXIS 84826 (S.D. Ohio Jun. 17, 2008).
[91] *Id.* at *23.

information about the time, manner, and context of the purported misrepresentations.[92]

In this case, Plaintiff Rieder cites to statements made by sales representative Mark Powell to Dr. Konold, which he argues show that Defendants' representatives made statements about the safety of its product "without disclosing the risk of long-term kidney injury."[93] Plaintiff Rieder also testified about a commercial he saw, and argues that it contained "no mention of possible kidney disease."[94] Plaintiff Rieder's allegations and his arguments about the purported misrepresentations boil down to the same thing – that the Defendants affirmative statements were misleading because they did not adequately warn of the risk of kidney disease. This is a classic failure to warn claim.

Plaintiff Rieder asserts that his claims are more similar to the claims of misrepresentation and fraud in other cases that were found not to be abrogated by OPLA.[95] I disagree. None of the four cases cited by Plaintiff Rieder involved a pharmaceutical product. While *Musgrave* involved a medical device, the plaintiff's

---

[92] *Id.* at *24-25.
[93] PSC's Summ. J. Opp'n Mem. in *Rieder* 23.
[94] PSC's Summ. J. Opp'n Mem. in *Rieder* 21-22.
[95] PSC's Summ. J. Opp'n Mem. in *Rieder* 19-22 (citing *Meta* , 2015 U.S. Dist. LEXIS 178781; *Musgrave v. Breg, Inc.*, No. 2:09-cv-1029, 2011 U.S. Dist. LEXIS 99491 (S.D. Ohio Sept. 2, 2011); *CCB Ohio LLC v. Chemque, Inc.*, 649 F. Supp. 2d 757 (S.D. Ohio 2009); *Elward v. Electrolux Home Prods., Inc.*, 264 F. Supp. 3d 877 (N.D. Ill. 2017)).

claims regarding fraudulent concealment and omissions were not abrogated by OPLA because the plaintiff's claim purportedly went to concealment of the regulatory status of the device and whether a specific use had been approved.[96] Plaintiff Rieder's misrepresentation and fraud claims are based upon the failure to include adequate warnings of kidney injuries, which is at its core the basis of his product liability claim.

Plaintiff Rieder's claims for negligent and fraudulent misrepresentation and fraud are, at their core, also based on upon the failure to provide an adequate warning of the risks of kidney injury. For this reason, consistent with the line of cases referenced above, I recommend that Defendants' motion for summary judgment be granted as to Counts VIII, IX and X.[97]

III. CONCLUSION

For the reasons set forth above, I recommend that the Defendants' motion for summary judgment be granted as to Counts VI (Breach of Express Warranty), VIII (Negligent Misrepresentation), IX (Fraud and Fraudulent Misrepresentation), and X (Fraudulent Concealment). I recommend that Defendants' motion for summary

[96] *Musgrave*, 2011 U.S. Dist. LEXIS 99491, at *28-29. The PSC argues that the holdings in *Johnson* and *Hendricks* make it hard to comprehend how a manufacturer could ever violate its general duty not to deceive. PSC's Summ. J. Opp'n Mem. in *Rieder* 24-25. *Musgrave* provides an example of such a situation.

[97] Given my recommendation that Plaintiff Rieder's negligent misrepresentation claims are abrogated by OPLA, this recommendation need not and does not address whether Plaintiff Rieder's negligent misrepresentation claims would be permitted under Ohio law if they were not abrogated by OPLA.

judgment be denied as to Counts I (Strict Product Liability) and III (Strict Product Liability – Failure to Warn), and be denied as moot as to Counts II (Strict Product Liability – Design Defect), IV (Negligence), V (Negligence *Per Se*), VII (Breach of Implied Warranty), and XI (Violation of Ohio State Consumer Protection Laws).

A proposed order is attached.

Respectfully submitted,

Date: July 19, 2022

ELLEN REISMAN
Special Master